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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/673,476

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Stewart Cole

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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,476

Applicant(s)

COLE ET AL.

Examiner

Jehanne Souaya Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/18/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner reviewing your application at the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Jehanne Sitton.
2. Currently, claims 53-58 as filed in the 11/21/03 amendment are under consideration at this time. The instant application has been withdrawn from issue as 102(b) art was found pertaining to the instant claims. Additionally, 112/1st paragraph issues with regard to Written Description remain for claims 57 and 58. The examiner's amendment mailed 1/9/2004 has not been entered. Accordingly, the recitation of "or fragments thereof" remains in the preamble of claim 53. The following rejections are newly applied and constitute the complete set being presently applied to the instant application. This action is NON-FINAL.

Claim Rejections - 35 USC § 112

Indefinite

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 53-58 are indefinite in the numbering system of the mycobacterium tuberculosis genome. The numbering system is not with regard to SEQ ID NO 1, which is the only reference used in the claims. Accordingly, without a reference point, the numbering system

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is arbitrary. It is suggested that instead of the numbering system used in the claims, that the claims be amended to use the nucleotide positions from SEQ ID NO: 1.

B) Claim 53 is indefinite as the preamble states that the polynucleotide comprises an open reading frame, however nucleotide 1,696,015 to 1,696,441 of the mycobacterium tuberculosis genome is not taught by the specification to “comprise” an open reading frame. The specification at page 12 teaches that an open reading frame occurs from position 1,695,944 to 1,696,441. Accordingly, the recitation of “comprises an open reading frame” is indefinite as it appears that part (a) of claim 53 does not actually comprise an open reading frame but is only a partial sequence of an open reading frame.

Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to unspecified sequences with any magnitude or content that hybridize to any of the polynucleotides of SEQ ID NOS 53-56 under any (claim 57) as well as specified (claim 58) conditions. Such recitation encompasses variants, mutants, and homologs as well as completely unrelated sequences in comparison to the sequences recited in claims 53-56.

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Even though claim 58 recites specific stringent conditions, such conditions still permit sequences that are not completely complementary to the recited sequences to hybridize. Such sequences encompass a very large genus of sequences with mutations or polymorphisms, such that the genus encompassed by the claims includes variants, mutants, homologs, as well as unrelated sequences to the sequences recited in claims 53-56. The single sequence of SEQ ID NO: 1, which contains 10 complete and 1 partial ORF, is not representative of the large genus of possible undisclosed nucleic acids that are encompassed by such broad claim language.

Additionally, the specification does not demonstrate any function or activity for the proteins encoded by the recited ORFs contained within SEQ ID NO 1. As such no structure/function correlation is present in the claims to further define the large genus. It is noted that the recitation of "hybridization" or specific hybridization conditions does not provide sufficient structure/function correlation between the listed sequences and the sequences encompassed by the claims because the ability of a sequence to hybridize to another is based on its primary nucleotide sequence and is a structural, not functional limitation. In other words, a single nucleotide change between two sequences would not affect hybridization between the two sequences in most cases, however such alteration could abolish the activity or function of the encoded protein. For these reasons, the artisan would not be able to determine which sequences fell within the broad genus of nucleic acid molecules other than by SEQ ID NO.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of sequences consisting of SEQ ID NO: 1 or sequences comprising each individual full length ORF, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. While one of skill in the art would be able to perform experiments to determine which sequences would hybridize to the sequences listed in claims 53-56, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796, 12/12/1995).

The claim is drawn to unspecified fragments of SEQ ID NO: 1. Brennan teaches every possible isolated trimer nucleic acid which are considered “fragments” of SEQ ID NO: 1 and anticipates the instant claim.

9. Claims 57 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank accession number AD000001 (December 1996).

The accession number teaches a sequence from *M. tuberculosis* that would hybridize to the indicated sequences from claims 53-56, including under the conditions specified in claim 58 (alignment provided: the complement of the accession number from position 4624 to position 17345 is 99% identical to SEQ ID NO: 1).

Conclusion

10. No claims are presently allowable. Claims 54-56 are free of the cited prior art.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Jehanne Sitton
Primary Examiner
Art Unit 1634

6/9/04